

I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claim 1. (currently amended) An oral dosage form, comprising an orally therapeutically effective combination dose of an opioid agonist, and naltrexone or a pharmaceutically acceptable salt thereof; wherein the combination is selected from the group consisting of:

naltrexone or a pharmaceutically acceptable salt thereof and hydrocodone or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.03:1 to about 0.27:1;

naltrexone or a pharmaceutically acceptable salt thereof and oxycodone or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.037:1 to about 0.296:1;

naltrexone or a pharmaceutically acceptable salt thereof and codeine or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.005:1 to about 0.044:1;

naltrexone or a pharmaceutically acceptable salt thereof and hydromorphone or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.148:1 to about 1.185:1;

naltrexone or a pharmaceutically acceptable salt thereof and levorphanol or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.278:1 to about 2.222:1;

naltrexone or a pharmaceutically acceptable salt thereof and meperidine or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.0037:1 to about 0.0296:1;

naltrexone or a pharmaceutically acceptable salt thereof and methadone or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.056:1 to about 0.444:1; and

naltrexone or a pharmaceutically acceptable salt thereof and morphine or a pharmaceutically acceptable salt thereof, in a weight ratio of from about 0.018:1 to about 0.148:1

~~the dosage form having a ratio of naltrexone or pharmaceutically acceptable salt thereof to opioid agonist that provides a combination product which is analgesically effective when the combination is administered orally, but which is aversive in physically dependent human subjects when administered at the same dose or at a higher dose than the therapeutically effective dose.~~

Claim 2. (cancelled)

Claim 3. (previously presented) The oral dosage form of claim 1, wherein the opioid agonist is
hydrocodone or a pharmaceutically acceptable salt thereof.

Claim 4. (cancelled)

Claim 5. (currently amended) The oral dosage form of claim 3, wherein the ratio of
naltrexone or pharmaceutically acceptable salt thereof to hydrocodone or pharmaceutically acceptable salt thereof is from about 0.05:1 to about 0.20:1.

Claim 6. (cancelled)

Claim 7. (original) The oral dosage form of claim 1, further comprising an additional non-opioid drug selected from the group consisting of an NSAID, a COX-2 inhibitor, acetaminophen, aspirin, an NMDA receptor antagonist, a drug that blocks a major intracellular consequence of NMDA-receptor activation, an antitussive, an expectorant, a decongestant, an antihistamine and mixtures thereof.

Claim 8. (original) The oral dosage form of claim 1, further comprising one or more pharmaceutically acceptable inert excipients.

Claim 9. (cancelled)

Claim 10. (previously presented) The oral dosage form of claim 1, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 11. (original) The oral dosage form of claim 1, further comprising a sustained release carrier which imparts sustained release properties to said opioid agonist.

Claim 12. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to oxycodone is from about 0.037:1 to about 0.296:1.~~

Claim 13. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is codeine or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to codeine is from about 0.005:1 to about 0.044:1.~~

Claim 14. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is hydromorphone or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to hydromorphone is from about 0.148:1 to about 1.185:1.~~

Claim 15. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is levorphanol or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to levorphanol is from about 0.278:1 to about 2.222:1.~~

Claim 16. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is meperidine or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to meperidine is from about 0.0037:1 to about 0.0296:1.~~

Claim 17. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is methadone or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to methadone is from about 0.056:1 to about 0.444:1.~~

Claim 18. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is morphine or a pharmaceutically acceptable salt thereof, ~~and the ratio of naltrexone to morphine is from about 0.018:1 to about 0.148:1.~~

Claim 19. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof, and the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to oxycodone or pharmaceutically acceptable salt thereof is from about 0.056:1 to about 0.222:1.

Claim 20. (currently amended) The oral dosage form of claim 1, wherein said opioid agonist is codeine or a pharmaceutically acceptable salt thereof, and the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to codeine or pharmaceutically acceptable salt thereof is from about 0.0083:1 to about 0.033:1.

Claims 21 - 35 (cancelled).

Claim 36. (New) The oral dosage form of claim 3, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 37. (New) The oral dosage form of claim 12, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 38. (New) The oral dosage form of claim 13, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 39. (New) The oral dosage form of claim 14, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 40. (New) The oral dosage form of claim 15, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 41. (New) The oral dosage form of claim 16, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 42. (New) The oral dosage form of claim 17, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 43. (New) The oral dosage form of claim 18, wherein said naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 44. (New) The oral dosage form of claim 3, wherein the opioid agonist is hydrocodone bitartrate.

Claim 45. (New) The oral dosage form of claim 12, wherein the opioid agonist is oxycodone hydrochloride.

Claim 46. (New) The oral dosage form of claim 13, wherein the opioid agonist is codeine phosphate.

Claim 47. (New) The oral dosage form of claim 14, wherein the opioid agonist is hydromorphone hydrochloride.

Claim 48. (New) The oral dosage form of claim 15, wherein the opioid agonist is levorphanol tartrate.

Claim 49. (New) The oral dosage form of claim 16, wherein the opioid agonist is meperidine hydrochloride.

Claim 50. (New) The oral dosage form of claim 17, wherein the opioid agonist is methadone hydrochloride.

Claim 51. (New) The oral dosage form of claim 18, wherein the opioid agonist is morphine sulfate.

Claim 52. (New) The oral dosage form of claim 14, wherein the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to hydromorphone or pharmaceutically acceptable salt thereof is from about 0.222:1 to about 0.889:1.

Claim 53. (New) The oral dosage form of claim 15, wherein the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to levorphanol or pharmaceutically acceptable salt thereof is from about 0.417:1 to about 1.667:1.

Claim 54. (New) The oral dosage form of claim 16, wherein the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to meperidine or pharmaceutically acceptable salt thereof is from about 0.0056:1 to about 0.022:1.

Claim 55. (New) The oral dosage form of claim 17, wherein the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to methadone or pharmaceutically acceptable salt thereof is from about 0.083:1 to about 0.333:1.

Claim 56. (New) The oral dosage form of claim 18, wherein the weight ratio of naltrexone or pharmaceutically acceptable salt thereof to morphine or pharmaceutically acceptable salt thereof is from about 0.028:1 to about 0.111:1.